



July 28, 2019

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Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Attention: Docket ID No. EPA-HQ-OPP-2018-0258

Mr. Jones:

The Lawn and Horticultural Products Work Group (LHPWG) on behalf of its members is pleased to submit comments to the Environmental Protection Agency's Office of Pesticide Programs (OPP) concerning the draft guidance document entitled "Guidance for Plant Regulator Label Claims, Including Plant Biostimulants."

Statement of Interest

The LHPWG, operating under the auspices of the Household & Commercial Products Association (HCPA), formerly the Consumer Specialty Products Association (CSPA) provides a unified voice for companies engaged in the unique market of lawn and horticultural products. LHPWG member companies manufacture more than 75 percent of domestically produced conventional specialty pesticides and fertilizers products utilized in the United States; including consumer household, lawn and garden, golf courses and other professional turf and lawn care. These specialty pesticides and fertilizer products are licensed; registered and sold to consumers and professional applicators in all 50 states.

Our members devote a significant amount of time and resources to registering their products with the EPA's Office of Pesticide Programs. The incorporation of "Biostimulant(s)" into specialty products formulated for consumers is a rapidly growing segment of the industry, as companies attempt to differentiate their products from others. The rapid growth of this market has presented challenges to both state control officials and registrants as we move forward without a clear understanding of what label claims are acceptable and when a "Biostimulant" needs to be registered as a pesticide. Therefore, our members have a significant interest in this topic and the agency's role.

General Comments:

This Draft Guidance document provides a lot of information but very little guidance. By focusing on claims that might be considered to belong to EPA-regulated products, the EPA misses an opportunity to provide clarity based on analysis of function. Instead of claims, the existing regulatory framework should be used to show where Plant Biostimulants (PBS) fit. We suggest that the agency needs to include a "decision tree" to provide guidance on key divisions between product classes to the regulated community. There are literally thousands of "natural substances" that have the potential to be PGRs; we have attached a DRAFT "decision tree" for plant hormones to serve as a template for your consideration. The Guidance Document does provide an opportunity for the United States Environmental Protection Agency's Office of Pesticide Programs (OPP) to gain a better understanding of the regulation of fertilizer.

The Draft Guidance document correctly describes several classes of products which are not pesticides (Plant nutrients and trace elements, Plant inoculants, Soil amendments and Vitamin-hormone products). These four groups of products encompass a wide variety of products, some of which today are used as PBS. However, this list is not inclusive of all classes of PBS.

While there is no federal statute that gives any Federal Agency jurisdiction over the regulation of fertilizer ("plant nutrients"), the registration and distribution of fertilizer is regulated by state law. 48 states have passed legislation that controls the registration and distribution of fertilizer throughout the United States. The Association of American Plant Food Control Officials (AAPFCO) was created in 1946 to "promote uniform and effective legislation, definitions, rulings and enforcement practices" for fertilizer products sold throughout the United States. State Control Officials are solely responsible for the regulation of fertilizer in the United States. To the extent that some states regulate soil amendments, AAPFCO Officials also contribute to definition of which products are soil amendments.

The EPA has proposed the following definition for a "plant biostimulant" it is a naturally-occurring substance or microbe that is used either by itself or in combination with **other naturally-occurring substances** or microbes for the purpose of stimulating natural processes in plants or in the soil in order to, among other things, improve nutrient and/or water use efficiency by plants, help plants tolerate abiotic stress, or improve the physical, chemical, and/or biological characteristics of the soil as a medium for plant growth.

This definition is overly broad, and the term "with other naturally occurring substances or microbes" can be construed to mean almost anything. We propose that the definition should be limited to specific substances which by themselves act to stimulate growth or improve soil conditions. The definition would then say: a "plant biostimulant" it is a naturally-occurring substance or microbe that is used for the purpose of stimulating natural processes in plants or in the soil in order to, among other things, improve nutrient and/or water use efficiency by plants, help plants tolerate abiotic stress, or improve the physical, chemical, and/or biological characteristics of the soil as a medium for plant growth.

This proposed definition excludes combinations of plant biostimulants and inorganic fertilizers, as inorganic fertilizer products are not "**naturally-occurring substances**." There are several "plant biostimulants" that are already incorporated into the specialty fertilizer products during the production process (e.g., Bacillus Subtillis, Humic Acid, etc.). So, inorganic fertilizers should be included in the EPA definition.

When considering specialty (non-crop) fertilizer products combined with biostimulants or pesticides, OPP must rely upon the following definitions found in 40 CFR Part 152 or define terms:

1) Plant nutrients are "...product[s] consisting of one or more macronutrients, or micronutrient trace elements necessary to normal growth of plants and in a form readily useable by plants" [40 CFR 152.6(g)(1)].

2) Plant inoculants are "...product[s] consisting of microorganisms to be applied to the plant or soil for the purpose of enhancing the availability or uptake of plant nutrients through the root system" [40 CFR 152.6(g)(2)].

34) Soil amendments are (which include soil additives and soil conditioners) "...product[s] containing a substance or substances intended for the purpose of improving soil characteristics favorable for plant growth" [40 CFR 152.6(g)(3)]

4) Vitamin-hormone products are "...product[s] consisting of a mixture of 1) plant hormones, 2) plant nutrients, 3) inoculants, or 4) soil amendments is not a "plant regulator" under section 2(v) of FIFRA, provided it meets the following criteria:

- (1) The product, in the undiluted package concentration at which it is distributed or sold, meets the criteria... for Toxicity Category III or IV; and
 - (2) The product is not intended for use on food crop sites; and is labeled accordingly."
- [40 CFR 152.6(f)]

EPA uses the term "plant hormones" above and there is no EPA definition for this term. **Plant hormones** are "... naturally occurring hormones extracted from algae, such as such as auxins, cytokinins, and gibberellins. Is this the EPA definition?

As you can see, these EPA definitions above are all dated, and we believe that the EPA should consider revising these definitions to reflect recent developments in soil science.

EPA should establish and maintain a list of known Plant Growth Regulators (PGR) on their OPP website.

The "**Plant nutrients**" definition in Part 152 should be revised with a new three-part definition for "Macronutrients, Secondary Nutrients and Micronutrients" and all the elements shall be listed.

The "**Plant Inoculants**" definition in Part 152 should be revised and replaced with a new definition that recognizes three (3) classes of inoculants: "1) Biofertilizers, 2) Biopesticides and 3) Plant Resistance Stimulants" based upon their mode of action. One class: Biopesticides would clearly fall under the EPA's jurisdiction.

The "**Soil Amendment**" definition in Part 152 should be revised and replaced with the AAPFCO definition which reads "any substance or a mixture of substances which is intended to improve the physical, chemical, biochemical, biological or other characteristics of the soil."

New definitions in Part 152 would help both companies and EPA personnel quickly determine whether EPA approval was necessary.

New definitions would allow companies that wanted to innovate and create new enhanced efficiency fertilizer (EEF) products to clearly understand the regulatory implications of combining a specialty fertilizer product (plant nutrients) with a regulated "biostimulant" [1) EPA listed plant hormone (PGR) or 2) "biopesticide" Plant Inoculant].

Formulators would know that other combinations of specialty fertilizers (plant nutrients) and "biofertilizers, plant resistant stimulants or soil amendments would not fall under the EPA's jurisdiction

Further, we suggest that the existing definitions cause confusion by how they are applied. For instance, Seaweed extracts (Table 4 in the Draft Guidance) are Pesticides under FIFRA. Yet Seaweed extracts don't have a defined content of PGRs (due to natural variation) and so might reasonably be a Vitamin-hormone product. This confusion is precisely why better definitions are needed, and better definitions that focus on function rather than claims.

The Draft Guidance states... **"Plant Regulators and Product Label Claims:** In determining what natural substances are considered plant regulators, and what may constitute a plant regulator claim on a product label, the mode of action of the substance(s) and associated label claim(s) must be congruent with the intent of the plant regulator definition. Based solely on the FIFRA section 2(v) "plant regulator" definition, a naturally occurring substance would be considered a "plant regulator," and a product label claim would be considered a "plant regulator claim" if:

The substance or mixture of substances, through physiological action:

1. Accelerates or retards the rate of plant growth;
2. Accelerates or retards the rate of plant maturation;
3. Or otherwise alters the behavior of plants or the produce thereof;

and if the substance or mixture of substances does not fall under one of the exclusion categories listed in 40 CFR 152.6(f) & (g) as vitamin-hormone products, plant nutrients, plant inoculants or soil amendments; or under 40 CFR 152.8(a) as a fertilizer."

This definition is problematic because it sends the regulated community back to a list of exclusions [40 CFR 152.6(f) & (g) & 40 CFR 152.8(a)] rather than adequately defining what PGRs do.

PGRs can retard the uniform growth of the plant or alter the normal development of the plant to the grower's benefit. A grower will buy and apply a PGR to their plants because he or she wants to:

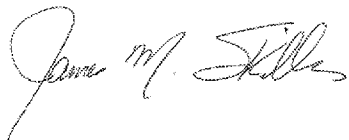
- 1) control/delay abscission/development/ripening/senescence,
- 2) induce/promote /retard/suppress flowering,
- 3) induce/promote/retard/suppress bud break or
- 4) induce/promote/retard/suppress seed germination.

These benefits are why PGRs are applied to specific plants at specific times.

We suggest the following definition for PGRs: the substance or mixture of substances that once applied; alter through physiological action alter the normal development of the targeted plant(s) to benefit the grower.

Thank you for the opportunity to comment on the draft guidance document entitled "Guidance for Plant Regulator Label Claims, Including Plant Biostimulants." Please do not hesitate to contact me should you require additional information to clarify any of the suggestions we provided.

Sincerely,

A handwritten signature in cursive script, appearing to read "James M. Skillen".

James M. Skillen on behalf of the LHPWG

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